JUDGE RAKOFF

07 CV 6227

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| JERRY TWINDE, On Behalf of Himself and All Others Similarly Situated,<br><br>Plaintiff,<br><br>vs.<br><br>THRESHOLD PHARMACEUTICALS, INC., HAROLD "BARRY" E. SELICK and JANET I. SWEARSON,<br><br>Defendants. | Civil Action No.<br><br>COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS<br><br>DEMAND FOR JURY TRIAL |

## SUMMARY AND OVERVIEW

1. This is a securities class action on behalf of all purchasers of the common stock of Threshold Pharmaceuticals, Inc. ("Threshold" or the "Company") between 2/4/05 and 7/14/06 (the "Class Period"), including purchasers in Threshold's 2/4/05 $37 million initial public offering ("IPO") and Threshold's 10/12/05 $65 million follow-on offering ("Follow-on Offering"), against Threshold and certain of its current and former officers and directors for violations of the Securities Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act").

2. Threshold discovers, develops, and commercializes small molecule therapeutics based on "Metabolic Targeting." According to defendants' Class Period statements, by targeting differences in the metabolism of normal and diseased cells, Threshold would develop drugs that were less toxic to healthy tissues. This approach was said to target abnormal glucose metabolism – a fundamental property of most solid tumors and other diseases. According to defendants, Metabolic Targeting could be used in the treatment of cancer and benign prostatic hyperplasia ("BPH"), a disease characterized by overgrowth of the prostate. Distinguishing this treatment from others available, Metabolic Targeting was said to provide the capability of treating not only rapidly dividing tumor cells, but also the slower dividing tumor cells that generally evade traditional therapies and ultimately contribute to relapse. A drug named TH-070, utilizing Threshold's patented Metabolic Targeting process, was described as the Company's ***"lead product candidate"*** for the treatment of symptomatic BPH.

3. In preparation for the Company's 2/05 IPO, between 3/04 and 8/04, defendants conducted a so-called "Phase II" study of TH-070 on 30 men at Bari University in Italy ("Bari Phase II study"). The Bari Phase II study was purportedly a "proof of concept" test, *i.e.*, the first study testing the use of Metabolic Targeting in the treatment of BPH. During the study, four men dropped out, leaving only 26 participants. ***There was no placebo arm of the study, which was highly***

***relevant considering the small number of participants***. Nonetheless, in the Company's registration statement and prospectus for its 2/05 IPO, defendants stated that based on the purportedly conclusive positive results of the Bari Phase II study:

- "***For the treatment of cancer, [the Company] believe[d] that [its] product candidates based on Metabolic Targeting [could] be broadly applied to the treatment of most solid tumors and [had] the potential to significantly increase the effectiveness of existing therapies***."
- "***Metabolic Targeting provide[d] the opportunity to treat not only rapidly dividing tumor cells, which [were] targeted by chemotherapy and radiation, but also slowly dividing tumor cells that generally evade[d] these traditional therapies and ultimately contribute[d] to relapse***."
- "***For the treatment of BPH, [the Company] believe[d] that Metabolic Targeting w[ould] enable [it] to develop a new class of drugs to treat the disease more rapidly and effectively, with fewer side effects than current therapies***."
- Defendants "***believe[d] that [their] focus on Metabolic Targeting, combined with [their] expertise in medicinal chemistry and drug development, provide[d] [them] with the capability to identify, discover and develop novel therapies***."
- Threshold had "completed enrollment," was "evaluating interim data," and defendants had "***observed statistically significant improvements in all variables measured by day 28.***"
- "***In the study, TH-070 was well tolerated with no therapy-related side effects***."
- "***Based on these interim Phase 2 results,*** [defendants were] designing a registrational program for TH-070 to treat symptomatic BPH."
- "TH-070 [was] an orally administered small molecule that ha[d] been reported to inhibit the enzyme that catalyzes the first step in glycolysis."
- "***TH-070 offer[ed] the potential to treat symptomatic BPH via a novel mechanism, by reducing the prostate size through Metabolic Targeting***."
- "***By directly inhibiting glycolysis in prostate cells," defendants "expect[ed] TH-070 to reduce the size of the prostate more rapidly than current medical treatments, without the attendant side effects, which include[d] decreased libido, impotence and cardiovascular effects***."

4. Based on the purported success achieved in the Bari Phase II study, the Company completed its $37 million IPO in 2/05, conducted additional clinical trials, filed its new drug

application ("NDA") with the Food and Drug Administration ("FDA") in late 2005, and completed the $65 million Follow-on Offering in 10/05. However, on 5/11/06, defendants would shock the market when they were forced to disclose that:

> ***As a result of abnormalities observed in liver enzyme levels in 6 subjects in ongoing clinical trials, the FDA (U.S. Food and Drug Administration) has placed the U.S. TH-070 program on partial clinical hold and has requested that the Company provide additional information related to the drug's acceptable dose and duration of treatment in BPH patients. These abnormalities include 3 serious adverse events observed at 3 months of dosing in the phase 3 European/Canadian clinical trial and 3 additional observations of elevated liver enzymes that occurred in other ongoing clinical trials.***

5. While defendants had known for years of TH-070's propensity to cause liver toxicity, the IPO and the Follow-on Offering prospectuses concealed it.

6. In order to provide the market with (false) assurance that TH-070 was still a commercially viable drug candidate, defendants stated on 5/11/06 that virtually all 567 patients enrolled in the European Phase III study had completed 28 days of dosing and that that the "[d]ata from these patients combined with that from the 216 U.S. phase 2 patients [would] be evaluated and [defendants would] inform the Company's next steps for this program and its response to the FDA."

7. Despite defendants' attempts during the 5/11/06 conference call with investors to reassure the market that TH-070 could still potentially prove efficacious enough to permit the FDA to overlook its toxicity issues, *i.e.*, that the drug's benefits would outweigh its potential toxicity and that FDA approval was still probable, the Company's stock declined, falling precipitously over 77% on 5/11/06 – by $10.56 per share to $3.44 per share on more than 85 times its average daily trading volume.

8. However, on 7/17/06, the proverbial other shoe would drop. The Company was forced to concede that ***TH-070 provided no benefit whatsoever in the alleviation of prostate enlargement*** and that ***"[b]ased on the safety and efficacy results of these trials, Threshold***

***plan[ned] to discontinue development of TH-070 for BPH" altogether.*** On this news the Company's stock fell again by 51% to $1.55 per share on very high volume.

9. The true facts, which were known by each of the defendants but concealed from the investing public during the Class Period, were as follows:

(a) the Bari Phase II study results did not properly reflect the significance or relevance of the different types of BPH;

(b) the Company's Class Period the statements grossly overstated TH-070's potential treatment population based on the different responses between those with severe BPH and moderate BPH;

(c) despite the Bari Phase II study's publicly released conclusions that TH-070 was appropriate for the treatment of severe BPH with high risk of progression, defendants had proceeded with two full-scale studies of TH-070 for treatment of moderate BPH ***without any basis upon which to conclude it would be efficacious or safe;*** and

(d) defendants knew TH-070 had a history of promoting high liver toxicity.

10. As a result of the defendants' false and misleading statements, Threshold's stock traded at inflated levels during the Class Period, trading as high as $16.52 per share in 4/06, allowing the Company to sell $102 million worth of Threshold common stock in the IPO and the Follow-on Offering.

## JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to §§11, 12(a)(2) and 15 of the Securities Act [15 U.S.C. §§77k, 77l(a)(2) and 77o] and §§10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the SEC [17 C.F.R. §240.10b-5].

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, and §22 of the Securities Act and §27 of the Exchange Act.

13. Venue is proper in this District pursuant to §22 of the Securities Act and §27 of the Exchange Act. Many of the false and misleading statements were made in or issued from this District, including:

(a) The underwriters in Threshold's IPO and Follow-on Offering are all located in and conducted underwriting out of this District, including: Banc of America Securities (with a significant office in New York City ("NYC")); William Blair & Company (headquartered in Chicago with a significant office in NYC); Morgan Stanley (headquartered in NYC); CIBC World Markets (headquartered in Toronto, Canada, with a significant U.S. office in NYC); and Lazard Capital Markets (headquartered in NYC).

(b) The Company and its underwriters and venture capital financers conducted a series of road shows in this District, including: a 1/24/04 U.S. Bancorp Piper Jaffray Annual Health Care Conference on Wednesday, January 28, 2004 at The Pierre hotel in NYC; the CIBC World Markets Annual Biotechnology and Specialty Pharmaceuticals Conference on 4/5/05 at The Millennium Broadway Hotel in NYC; and the BioCentury Future Leaders in the Biotech Industry on 4/7/05 at the Millennium Broadway Hotel in NYC.

(c) The Company's 2/4/05 release advised investors to obtain the IPO prospectus from Banc of America Securities at 9 West 57th Street, New York, New York.

(d) The Company's 9/27/05 release advised investors to obtain the Follow-on Offering prospectus from the Morgan Stanley at 1585 Broadway, New York, New York.

(e) The Phase II trials of TH-070 were conducted in large part in New York at Accumed Research Associates, in Garden City, New York; at New York University School of Medicine, in NYC; and at the Weill Medical College of Cornell University, in NYC.

**THE PARTIES**

14. Plaintiff Jerry Twinde purchased Threshold common stock as described in the attached certification and was damaged thereby.

15. Threshold was incorporated in 2001 in Delaware. The Company's common stock trades on the NASDAQ under the ticker symbol THLD.

16. Defendant Harold "Barry" E. Selick ("Selick") is, and at all relevant times has been, Chief Executive Officer ("CEO") and a director of the Company, having joined Threshold in 2003.

17. Defendant Janet I. Swearson ("Swearson") served as Chief Financial Officer ("CFO") and Vice President, Finance and Administration of Threshold until her resignation in August 2006.

18. The individuals and entities named as defendants in ¶¶16-17 are referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Threshold's quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them but not to the public, each of these defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false

statements pleaded herein at ¶¶29-42, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

**SCIENTER**

**(Relevant to Exchange Act Claims Only)**

19. For purposes of the Exchange Act claims, in addition to the above-described involvement, each Individual Defendant had knowledge of Threshold's problems and was motivated to conceal such problems. Defendants Selick, as CEO, and Swearson, as CFO, were responsible for the reports and claims relating to TH-070 as well as the press releases issued by the Company. Each Individual Defendant sought to demonstrate that he or she could lead the Company successfully and generate the successful commercialization of TH-070, including obtaining FDA approval.

20. Defendants were motivated to engage in the fraudulent practices alleged herein in order to obtain cash and stock bonuses, collectively worth tens of millions of dollars, together with consummating the Company's $37 million IPO in 2/05 and its $65 million Follow-on Offering in 10/05.

**FRAUDULENT SCHEME AND COURSE OF BUSINESS**

**(Relevant to Exchange Act Claims Only)**

21. For purposes of the Exchange Act claims, each defendant is liable for (i) making false statements, ***or*** (ii) failing to disclose adverse facts known to him about Threshold. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Threshold common stock was a success, as it (i) deceived the investing public regarding Threshold's prospects and business; (ii) artificially inflated the price of Threshold stock; (iii) allowed defendants to obtain larger bonuses which were directly tied to the ***perceived*** successful efforts to bring the Company's drugs closer to commercialization; (iv) allowed defendants to arrange to sell and actually sell in excess of $102 million worth of Threshold common stock at artificially inflated prices in the

IPO and the Follow-on Offering; and (v) caused plaintiff and other members of the Class to purchase Threshold common stock at inflated prices.

**BACKGROUND**

22. Threshold, a development stage company, claimed to engage in the discovery, development, and commercialization of small molecule therapeutics for the treatment of BPH and cancer. Its product candidates included lonidamine (TH-070), which would be used for the treatment of BPH; Glufosfamide, for the treatment of pancreatic cancer; and 2-deoxyglucose, or 2DG, for the treatment of solid tumors. However, TH-070 was promoted to be the most commercially viable of the three potential drugs.

23. Before 3/04, 30 patients were recruited for the Bari Phase II study of TH-070 in Italy. Men between the ages of 50 and 80 were eligible for inclusion if they had experienced lower urinary tract symptoms for at least three months and met other criteria, including being able to comply with the prescribed treatment protocol and evaluations.

24. The Bari Phase II study was designed to compare baseline measurements of certain criteria to measurements on day 28.

25. After signing informed consent forms, 30 patients were enrolled and given TH-070 therapy between 3/04 and 8/04. During the study, four dropouts were registered, leaving only 26 patients with sufficient data.

26. The Bari Phase II study was a "proof of concept" study and it was the first study testing the use of TH-070 in the treatment of symptomatic BPH. ***There was no placebo arm of the study, which is highly relevant, especially considering the small number of patients.***

27. BPH severity and symptoms vary greatly. Patients for the initial Bari Phase II study were selected on the basis of the risk of disease progression and of developing complications. Before study entry, 50% of the patients were severely symptomatic and were taking alpha-blockers.

28. After completion of the Bari Phase II study, Threshold launched plans for a full-scale Phase II study in the United States and a full-scale Phase III study in Europe.

**DEFENDANTS' FALSE AND MISLEADING STATEMENTS**

29. On 2/4/05 Threshold issued a release entitled "Threshold Pharmaceuticals Announces Initial Public Offering," which stated in relevant part:

> Threshold Pharmaceuticals, Inc. announced today its initial public offering of 5,333,333 shares of common stock at a price of $7 per share. All of the shares are being offered by Threshold. The shares will trade on the NASDAQ National Market under the symbol "THLD".
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> * * *
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> ***The registration statement relating to the initial public offering of common shares has been declared effective by the Securities and Exchange Commission.***

30. Concerning the status of TH-070's FDA regulatory approval status, the registration statement and prospectus issued in connection with the IPO and declared effective by the Securities and Exchange Commission ("SEC") on 2/4/05 explained that:

- Threshold's "initial clinical focus [was] the treatment of cancer and benign prostatic hyperplasia, or BPH, a disease characterized by overgrowth of the prostate" and ***Threshold had "three product candidates."***
- TH-070 was Threshold's "***lead product candidate for the treatment of symptomatic BPH" and was "being evaluated in a Phase 2 clinical trial.***"
- "***Metabolic Targeting***" was a "***therapeutic approach*** that targets fundamental differences in energy metabolism between normal and certain diseased cells. To survive, these diseased cells rely predominantly on glycolysis, also called glucose metabolism, which is the process by which glucose is converted to energy. As a consequence, these cells consume more glucose than do normal cells. In cancer, this increased consumption of glucose has two causes: the process of a normal cell becoming a rapidly dividing cancer cell; and the exposure of a cell to the low oxygen conditions, also called hypoxia, within those regions of most solid tumors where cells are dividing slowly. When these cells shift energy production to glycolysis, they must increase the levels of the proteins needed to transport and metabolize glucose. Similarly, cells in BPH rely predominantly on glycolysis for energy production. ***Metabolic Targeting takes advantage of these metabolic differences to selectively target these diseased cells.***"

- "For the treatment of cancer, [the Company] ***believe[d] that [its] product candidates based on Metabolic Targeting [could] be broadly applied to the treatment of most solid tumors and [had] the potential to significantly increase the effectiveness of existing therapies.***"

- "***Metabolic Targeting provide[d] the opportunity to treat not only rapidly dividing tumor cells, which [were] targeted by chemotherapy and radiation, but also slowly dividing tumor cells that generally evade[d] these traditional therapies and ultimately contribute[d] to relapse***."

- "***For the treatment of BPH, [the Company] believe[d] that Metabolic Targeting w[ould] enable [it] to develop a new class of drugs to treat the disease more rapidly and effectively, with fewer side effects than current therapies***."

- Defendants "***believe[d] that [their] focus on Metabolic Targeting, combined with [their] expertise in medicinal chemistry and drug development, provide[d] [them] with the capability to identify, discover and develop novel therapies***."

- TH-070, Threshold's "***lead product candidate for the treatment of symptomatic BPH***, [was] being evaluated in a Phase 2 trial in Italy" and the "primary objective of this trial [was] to determine the safety and tolerability of TH-070 in patients with BPH."

- "In addition, ***patients [were] being evaluated for efficacy*** as measured by changes in specific variables that ha[d] been used in clinical trials of currently marketed BPH drugs ***to support their FDA approval***."

- Threshold had "completed enrollment," was "evaluating interim data," and defendants had "***observed statistically significant improvements in all variables measured by day 28.***"

- "***In the study, TH-070 was well tolerated with no therapy-related side effects***."

- "***Based on these interim Phase 2 results,*** [defendants were] designing a registrational program for TH-070 to treat symptomatic BPH."

- "TH-070 [was] an orally administered small molecule that ***ha[d] been reported to inhibit the enzyme that catalyzes the first step in glycolysis***."

- "***TH-070 offer[ed] the potential to treat symptomatic BPH via a novel mechanism, by reducing the prostate size through Metabolic Targeting***."

- "***By directly inhibiting glycolysis in prostate cells," defendants "expect[ed] TH-070 to reduce the size of the prostate more rapidly than current medical treatments, without the attendant side effects, which include decreased libido, impotence and cardiovascular effects***."

31. On 5/19/05, the Company issued a press release entitled "Threshold Pharmaceuticals ***Announces Positive Results From TH-070 Phase 2 Study in Treatment of Benign Prostatic Hyperplasia; Trial Shows Significant Sustained Improvement in Symptoms Six Months Off Therapy***," which stated in part:

> Threshold Pharmaceuticals Inc. today announced follow up results of a Phase 2 study of its investigational drug candidate, TH-070 (lonidamine) for the treatment of benign prostatic hyperplasia (BPH). ***Six months after cessation of treatment, BPH symptoms (IPSS) in patients remained significantly improved compared to baseline as were maximum urine flow, post void urine volume, and PSA.*** The trial, conducted in 2004 at the University of Bari, Italy, met its primary endpoint, a mean reduction in prostate volume at day 28 compared to baseline (-11.2%, p<0.001), and all other Day 28 endpoints. ***Based on promising data from the initial dose group of patients in this study, Threshold elected not to enroll a second higher dose group and instead plans to initiate a Phase 2 multi-center study in the US and a Phase 3 multi-center study in Europe for TH-070 to treat symptomatic BPH in mid 2005.***
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> In the reported trial, ***thirty patients with symptomatic BPH*** received TH-070 orally (150 mg) once daily for 28 days. ***The regimen was well tolerated, with no therapy-related adverse side effects***. Highlights of the post study follow-up results six months later include:
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> - Validated International Prostate Symptom Scores (IPSS) improved from a mean of 19.5 prior to treatment to 12.2 at Day 28 (p<0.001) with an additional improvement to 9.8 after six month follow-up.
> - Mean Maximum Urine Flow improved 34.3% from a mean of 9.4 mL/sec at baseline to 12.6 mL/sec at day 28 (p=0.002) and improved 45.6% to a mean of 13.7 mL/sec at six month follow-up (p<0.001).
> - PSA decreased on average by 17.8 percent from a mean of 3.6 at baseline to 2.8 ng/mL at Day 28 (p<0.001) and on average by 14.8% to a mean of 3.1 ng/mL at six month follow-up (p=0.012).
> - Mean PVR (Post-void residual urine volume) decreased by 52.5 percent from a mean of 82.1 cc at baseline to 31.6 cc at Day 28 (p<0.001) and to 39.0 cc at six month follow-up (p=.003).
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> "***The magnitude and rapidity of the patients' response to TH-070 are very encouraging in the pharmaceutical treatment of BPH***," said George Tidmarsh, founder of Threshold Pharmaceuticals. "We are especially pleased to see that the effect of TH-070 is sustained off therapy."

32. On 6/27/05, the Company issued a press release entitled "Threshold Pharmaceuticals Initiates Registrational Program of TH-070 for Treatment of Benign Prostatic Hyperplasia; U.S. Phase 2 Clinical Trials Underway," which stated in part:

> Threshold Pharmaceuticals, Inc. announced today the initiation of its registrational program of its investigational drug candidate, TH-070 (lonidamine), ***under a U.S. Food and Drug Administration IND***. The company has begun a U.S. Phase 2 clinical trial evaluating the dosing, safety and activity of TH-070 for the ***treatment of symptomatic benign prostatic hyperplasia (BPH)***. A Phase 3 multi-center European trial evaluating the safety and efficacy of TH-070 is expected to commence in mid 2005. BPH is a non-cancerous enlargement of the prostate that affects over 54 million men worldwide and at least 17 million men over the age of 40 in the United States.
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> The Phase 2 trial is a randomized, placebo controlled, double-blinded study that will be conducted at up to thirty centers across the United States. Approximately 200 patients will participate in the study for up to four and a half months. Patients will be randomized to receive placebo or one of four doses of TH-070 daily for 28 days, and will be followed off of therapy for an additional three months. The primary objective of this study is to investigate the dose-response relationship of TH-070 with respect to efficacy and safety.
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> Additionally, ***this study is designed to confirm the findings for 28 days of dosing previously announced by Threshold from a Phase 2 single center study conducted in 2004 at the University of Bari, Italy. That trial met its primary endpoint, a mean reduction in prostate volume measured by Trans-rectal Ultrasound (TRUS) at day 28 compared to baseline (-11.2%, p<0.001), and all other day 28 endpoints. Six months after cessation of treatment, BPH symptoms (International Prostate Symptom Scores) in patients remained significantly improved compared to baseline as were maximum urine flow, post-void urine volume, and PSA (Prostate Specific Antigen).***
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> "***Our U.S. trial demonstrates Threshold's ability to launch a major clinical program in the BPH setting," said Alan Colowick, chief medical officer of Threshold. "We are excited about the potential that this therapy may offer men suffering from the symptoms of BPH while addressing the underlying disease itself***. This trial complements a Phase 3 trial that will soon be initiated in Europe."
>
> Both studies will investigate the effects of TH-070 on clinically important efficacy endpoints, including impact on symptoms as measured by IPSS, prostate volume measured by TRUS, change in PSA, change in maximal flow rate of urine, and a change in post-void residual of urine.

> ***"The data thus far suggests that there is great promise for this treatment," said Dr. Claus Roehrborn, Chair of Urology at University of Texas, Southwestern and one of the lead investigators in the U.S. Phase 2 trial. "TH-070 has the potential to actually reverse the BPH process and bring relief to many men who suffer from this condition."***

33. On 7/28/05, the Company issued a press release entitled "Data for Threshold Pharmaceuticals' TH-070 to be Presented at American Urological Association Western Section Conference; Dr. Michael Brawer, M.D. to Appear August 2, 2005 in Vancouver," which stated in part:

> Dr. Brawer will present a paper entitled, "***28 Day Lonidamine Therapy Significantly Reduces Prostate Volume and Improves Urine Flow in Symptomatic Benign Prostatic Hyperplasia: Results of a Phase 2 Open-Label Study***" which will examine the effects of TH-070 on International Prostate Symptom Score (IPSS), maximum flow rate, residual urine and prostate volume in patients with BPH. ***The findings conclude that the use of the drug induces a rapid and significant improvement by Day 14 with further improvements at Day 28 that were sustained through Day 200.*** Patients continued to be followed through Month 6 and data on the durability of these effects will be presented.
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> * * *
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> Dr. Brawer will present additional analyses which support the conclusion that TH-070 is active in BPH. ***These analyses show that TH-070 improves symptoms in patients regardless of their baseline disease status in terms of severity of symptoms and prostate volume***. Additionally, improvements in urine flow rate correlated well with improvements in symptoms.

34. On 8/8/05, the Company issued a press release entitled "Threshold Pharmaceuticals Announces Initiation of Phase 3 Trial in Europe for the Treatment of Benign Prostatic Hyperplasia," which stated in part:

> Threshold Pharmaceuticals Inc. today announced the initiation of a Phase 3 clinical trial as part of a registrational program of its investigational drug candidate TH-070 (lonidamine). The study will measure the dosing, safety, and efficacy of TH-070 in subjects with symptomatic benign prostatic hyperplasia (BPH). The company has begun patient enrollment and will conduct the trials at nearly 60 investigational sites in selected European countries.
>
> The Phase 3 trial will be a randomized, placebo-controlled, double-blinded study, enrolling men 50-80 years of age with symptomatic BPH. Approximately 480

patients will participate in the study for up to four and a half months. The primary objective is to evaluate the efficacy of TH-070 (50 mg, 150 mg) compared to placebo as measured by IPSS (International Prostate Symptom Scores) in subjects with symptomatic BPH.

"***We are excited about the potential of this therapy based on promising Phase 2 clinical data***," said Alan Colowick, chief medical officer of Threshold. "This is another important clinical milestone in our registrational program. The Phase 3 European trial complements our Phase 2 trial recently begun in the United States."

***The study is also designed to confirm the findings for 28 days of dosing previously announced by Threshold from a Phase 2 single center study conducted in 2004 at the University of Bari, Italy. That trial met its primary endpoint, a mean reduction in prostate volume measured by trans-rectal ultrasound (TRUS) at day 28 compared to baseline (-11.2%, p<0.001), and all other day 28 endpoints. Six months after cessation of treatment, BPH symptoms (International Prostate Symptom Scores) in patients remained significantly improved compared to baseline as were maximum urine flow, post-void urine volume, and PSA (Prostate Specific Antigen).***

35. On 10/12/05, defendants issued a release entitled "Threshold Announces Follow-On Offering of 6,250,000 Shares of Common Stock," which stated in relevant part:

Threshold Pharmaceuticals, Inc. today announced a follow-on offering of 6,250,000 shares of its common stock at a price to the public of $10.46 per share. Threshold and certain stockholders of Threshold have granted to the underwriters an option to purchase up to an additional 937,500 shares of common stock to cover over-allotments, if any, within 30 days from the date of the prospectus. 468,750 of these shares may be sold by the selling stockholders, proceeds from which will not be received by the Company.

Morgan Stanley is acting as sole bookrunning manager and CIBC World Markets and Lazard Capital Markets are acting as co-managers of the offering.

36. Concerning TH-070's FDA approval status, the registration statement and prospectus issued in connection with the Follow-on Offering and declared effective by the SEC on 10/12/05 explained that:

- Threshold was a "biotechnology company focused on the discovery, development and commercialization of drugs based on Metabolic Targeting, ***an approach that targets fundamental differences in metabolism between normal and certain diseased cells***."

- Threshold was "***building a pipeline of drugs that [were] designed to selectively target tumor cells and abnormally proliferating cells so that the drugs [were] efficacious and less toxic to healthy tissues than conventional drugs, thereby providing improvements over current therapies***."

- Threshold ***had "three product candidates*** for these programs," for which it had "exclusive worldwide marketing rights" including "TH-070, [its] ***lead product candidate for the treatment of symptomatic BPH***."

- TH-070 had "***completed a Phase 2 clinical trial*** in Italy" and Threshold had "initiated a Phase 2 trial in the United States in June 2005 and a Phase 3 trial in Europe in August 2005, ***both of which [were] multi-centered, randomized, blinded and placebo controlled trials***."

- "Metabolic Targeting [was] a ***therapeutic approach*** that targets fundamental differences in energy metabolism between normal and certain diseased cells. To survive, these diseased cells rely predominantly on glycolysis, also called glucose metabolism, which is the process by which glucose is converted to energy. As a consequence, these cells consume more glucose than do normal cells. Metabolic Targeting takes advantage of these metabolic differences to selectively target these diseased cells."

- "Since BPH cells rely predominantly on glycolysis for energy production, ***[defendants] believe[d] that Metabolic Targeting w[ould] enable [them] to develop a new class of drugs to treat the disease more rapidly and effectively, with fewer side effects than current therapies***."

- "***For the treatment of cancer, [defendants] believe[d] that [the Company's] product candidates based on Metabolic Targeting c[ould] be broadly applied to the treatment of most solid tumors and ha[d] the potential to significantly increase the effectiveness of existing therapies***."

- "***Metabolic Targeting provide[d] the opportunity to treat not only rapidly dividing tumor cells, which are targeted by chemotherapy and radiation, but also slowly dividing tumor cells that generally evade these traditional therapies and ultimately contribute to relapse***."

- ***Defendants "believe[d] that [the Company's] focus on Metabolic Targeting, combined with [their] expertise in medicinal chemistry and drug development, provide[d] [them] with the capability to identify, discover and develop novel therapies***."

- ***TH-070 was "an orally administered small molecule that ha[d] been reported to inhibit glycolysis by inactivating hexokinase, the enzyme that catalyzes the first step in glycolysis***."

- "***By targeting the metabolism of glucose and other processes that [were] essential for prostate cell viability, TH-070 kill[ed] prostate cells, reducing the size of the prostate, and therefore m[ight] provide an effective treatment for symptomatic BPH***."

- ***Threshold had "completed a Phase 2 trial in Italy of TH-070 in 30 men with symptomatic BPH" and "[i]n this study, TH-070 appeared to be generally well tolerated when administered at a dose of 150 mg orally every day for 28 days***."

- ***TH-070 "appear[ed] to be active in treating BPH" and "[u]sing baseline values as a control, statistically significant changes in all efficacy endpoints were observed***."

- "***Based on these data demonstrating tolerability and important clinical activity***, an investigational new drug application, or IND, was submitted to the FDA in the second quarter of 2005."

37. On 3/1/06, the Company announced its fourth quarter and fiscal year 2005 financial results in a release which stated in relevant part:

> "We achieved all of our key corporate and clinical milestones for 2005 and are looking forward to achieving significant milestones in 2006," said Barry Selick, Threshold's chief executive officer. "Over the past year, we initiated two placebo-controlled, multi-center trials of TH-070 for BPH: a Phase 2 trial in the United States and a Phase 3 study in Europe . . . . ***In addition, we raised approximately $100 million in net proceeds through an initial public offering and a follow-on public offering, both of which were completed last year.***"

38. Concerning "Recent Highlights," the Company's 3/1/06 release stated:

- Initiated and continued to enroll patients in Phase 2 and Phase 3 trials of TH-070 for BPH;

- Published positive Phase 2 results for TH-070 in patients with BPH in *Reviews in Urology*;

- Raised net proceeds of $38 million through an IPO and an additional $62 million through a follow-on public offering; and

- Received important patents related to TH-070 and 2DG from the U.S. Patent and Trademark Office.

39. Concerning "2006 Guidance and Key Milestones," the 3/1/06 release stated the Company expected to reach the "following clinical milestones in 2006":

- Report results from a Phase 2 study in BPH with TH-070 by end of 2006;

- Report results from a Phase 3 study in BPH with TH-070 by end of 2006; and

* * *

- Commence three supportive studies with TH-070 . . . .

40. On 5/10/06, the Company announced its first quarter 2006 financial results, with Selick stating that Threshold "continued to achieve [its] clinical milestones with the completion of enrollment in both the Phase 2 and Phase 3 trials of TH-070 in BPH, and [that the Company] expect[ed] to report the results of these trials around the beginning of the fourth quarter." Defendants also reported the following "highlights:"

- Completed enrollment of Phase 3 trial of TH-070 in BPH patients;
- Completed enrollment of Phase 2 trial of TH-070 in BPH patients; [and]

* * *

- Received important patents related to TH-070 and 2DG from the U.S. Patent and Trademark Office.

41. Defendants also stated the Company anticipated "the following clinical milestones in 2006":

- Report results from ongoing Phase 2 and Phase 3 trials of TH-070 in BPH around the beginning of the fourth quarter of 2006; [and]

* * *

- Commence three supportive trials with TH-070 . . . .

42. Suddenly, on 5/11/06, the Company shocked the market by issuing a release entitled "Threshold Pharmaceuticals Announces Changes to TH-070 Clinical Development Program; ***FDA Placed Program on Partial Clinical Hold***; U.S. Phase 2 Study Dosing Completed; European/Canadian Phase 3 Clinical Trial Will Be Amended; Conference Call to Be Held Today at 5:00 p.m. EDT," which stated in part:

Threshold Pharmaceuticals, Inc., today announced changes in the status of its TH-070 clinical development program for BPH (Benign Prostatic Hyperplasia).

***As a result of abnormalities observed in liver enzyme levels in 6 subjects in ongoing clinical trials, the FDA (U.S. Food and Drug Administration) has placed the U.S. TH-070 program on partial clinical hold and has requested that the Company provide additional information related to the drug's acceptable dose and duration of treatment in BPH patients***. These abnormalities include 3 serious adverse events observed at 3 months of dosing in the phase 3 European/Canadian clinical trial and 3 additional observations of elevated liver enzymes that occurred in other ongoing clinical trials.

***The Company is amending the phase 3 European/Canadian trial to discontinue dosing***. 567 patients have been enrolled in this study, virtually all whom have completed 28 days of dosing. Data from these patients combined with that from the 216 U.S. phase 2 patients will be evaluated and will inform the Company's next steps for this program and its response to the FDA.

* * *

Lonidamine (TH-070) was originally approved for the treatment of cancer in 3 European countries in the mid-1980's. Published randomized clinical trials of Londiamine [sic] in approximately 3500 cancer patients did not reveal statistically significant elevations in liver function tests. ***In the Company's previous single center phase 2 TH-070 trial, one patient had transient elevated liver enzymes***.

43. During the conference call following the announcement, Selick admitted there was 20 years worth of data on the drug's use in Europe, ***including clinical data demonstrating a high propensity for liver toxicity***:

BARRY SELICK: Sure. As you know, the data for us come primarily from that which is published in the literature. ***I will remind you that the drug was approved in multiple European countries since the mid-1980s for the cancer indication. In the literature are approximately 80 published studies, around 20 of which are controlled clinical trials.*** In those controlled clinical trials, greater than 3500 patients are reported, and in those studies, there is not any evidence of statistically significant differences in liver toxicity between those patients who received Londiamine [sic] versus those who did not.

STEVE HARR: ***But there are trends, correct?***

ALAN COLOWICK: ***There are studies in which numerically, in some studies, the liver toxicity was higher numerically*** . . . .

44. During the 5/11/06 conference call, Alan Colowick, Threshold's Chief Medical Officer, disclosed the Company also had its own historical data demonstrating the drug's toxicity: "***We had a discussion with the FDA about this specific [liver toxicity] case on April 10, [2006], as well as the other data that we had available to us at that time across all of our studies.***"

45. Analysts quickly downgraded the Company's stock, and shares traded down to $3 per share, falling $10.89, or 77.8 %, on volume of over 33 million shares – more than 85 times the average daily trading volume over the previous 30 days. Despite the precipitous decline in the Company's stock price, investors retained some hope of the drugs potential approvability, as they were told during the 5/11/06 call that the FDA would not make a final determination on TH-070's fate until the drug's efficacy was determined, meaning that a highly efficacious drug could get approved despite higher than desirable toxicity:

> STEVE HARR: When will we have efficacy data?
>
> ALAN COLOWICK: Well, we expect now to -- as we've mentioned, all patients in the U.S. study have completed their days 28 dosing and in Europe now at this time, actually tomorrow, all patients there will have completed their 28-day dosing. ***So if what you mean by efficacy data are the data from these ongoing studies, we will get those in-house as quickly as we can and get them analyzed. We clearly expect that will occur during the third quarter.***
>
> * * *
>
> JOHN WILSON, ANALYST, ROBERT W. BAIRD & COMPANY: . . . I was just wondering if you could in any way provide clarity on the timeline for your response to the FDA.
>
> ALAN COLOWICK: Yes, John, I think what I can tell you is obviously we're going to put in as rapid and quality a response to this notification as we can. First of all, we have to receive the formal notification. We were informed yesterday afternoon by a telephone call. The FDA has up to 30 days to send that letter, although I think our reviewers in this division are trying to cooperate and get that to us sooner. We expect it could come sooner. Until we have that letter, there's a formal response that is required; it's called a complete response to the partial clinical hold. Until we have that letter, we can't say with certainty what it will take to address their concerns. ***I think we have a very good feeling of what it will take, based on our conversation yesterday, but until we see it in writing, we can't say with certainty.***

***I can tell you that we are going to do everything we can to get the clinical data -- that is the data in these roughly 800 patients from the European and U.S. Phase II studies and in particular the day-28 data from these patients. We will do everything we can to get that in-house just as rapidly as we possibly can. Then it will be a matter of analyzing those data. We've got some important, completed studies, preclinical talk studies that the FDA is just becoming aware of because they've just recently been completed and will have to tie those two things together, so that may take some time, although obviously it will be a number one priority in the Company.***

46. However, on 7/17/06, the proverbial other shoe dropped. The Company issued a release entitled "***Phase 2 and Phase 3 Clinical Trials of TH-070 in Benign Prostatic Hyperplasia (BPH) Do Not Meet Primary Endpoint***," which stated in part:

> Threshold Pharmaceuticals, Inc., today announced that its Phase 2 and Phase 3 trials of TH-070 did not meet their primary endpoints of symptomatic improvement as measured by IPSS (International Prostate Symptom Score). The Phase 2 trial did not generate a statistically significant dose response relationship and the Phase 3 trial did not achieve a statistically significant difference in IPSS between TH-070 and placebo. Based on the safety and efficacy results of these trials, Threshold plans to discontinue development of TH-070 for BPH.
>
> * * *
>
> ***The interim analysis of the Phase 2 data did not demonstrate a clear dose response in IPSS at one month of treatment.*** The mean IPSS change from baseline as measured following placebo run-in to one month of treatment ranged from -2.1 to -2.5 across the five dose groups, including the placebo control.
>
> ***The interim analysis of the Phase 3 data did not demonstrate a statistically significant difference in IPSS between either of the two drug dose groups (50mg and 150mg) and placebo. The mean IPSS change from baseline as measured following the placebo run-in to one month of treatment ranged from -1.9 to -2.9 and to three months of treatment ranged from -4.4 to -5.5. There was no statistically significant difference in any of the secondary endpoints*** with the exception of change in prostate specific antigen (PSA) which did show statistical significance at certain time points. Primary endpoint results are summarized below.
>
> The interim safety results from the Phase 2 and Phase 3 trials include seven cases of myalgia and four cases of testicular pain. Across all TH-070 clinical trials, there were 15 patients who had elevations in liver enzymes (as defined by elevations greater than three times the upper limit of normal), two of whom were in the placebo group. ***Six of the patients with elevated liver enzymes were deemed to have experienced serious adverse events.***

47. On this news the Company's stock price dropped 51% to close at $1.55 per share on 7/17/06, on very high volume.

48. The true facts, which were known by each of the defendants but concealed from the investing public during the Class Period, were as follows:

(a) the Bari Phase II study results did not properly reflect the significance or relevance of the different types of BPH;

(b) the Company's Class Period statements grossly overstated TH-070's potential treatment population based on the different responses between those with severe BPH and moderate BPH;

(c) despite the Bari Phase II study's conclusions that TH-070 was appropriate for the treatment of severe BPH with high risk of progression, defendants had proceeded with two full-scale studies of TH-070 for treatment of moderate BPH ***without any basis upon which to conclude it would be efficacious or safe;*** and

(d) defendants knew TH-070 had a history of promoting high liver toxicity.

49. As a result of the defendants' false statements, Threshold stock traded at inflated levels during the Class Period, allowing the Company to sell $102 million worth of Threshold securities in the IPO and Follow-on Offering.

## COUNT I

### For Violation of Section 11 of the Securities Act Against All Defendants

50. Plaintiff incorporates ¶¶1-17 and 22-48 by reference herein. This Count is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, and is asserted against all defendants. For purposes of this Count, plaintiff does not claim that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

51. The Registration Statements for the IPO and the Follow-on Offering were inaccurate and misleading, contained untrue statements of material facts, omitted facts necessary to make the statements made therein not misleading and omitted to state material facts required to be stated therein.

52. Defendant Threshold is the issuer of the common stock purchased by plaintiff and the Class. As such, Threshold is strictly liable for the materially inaccurate statements contained in the Registration Statements and the Prospectuses and the failure of the Registration Statements and Prospectuses to be complete and accurate.

53. The Individual Defendants each signed the Registration Statements either personally or through an Attorney-in-Fact and/or caused their issuance. The Individual Defendants each had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Registration Statements. They had a duty to ensure that such statements were true and accurate, that there were no omissions of material facts that would make the statements misleading and that the documents contained all facts required to be stated therein. In the exercise of reasonable care, the Individual Defendants should have known of the material misstatements and omissions contained in the Registration Statements and also should have known of the omissions of material fact necessary to make the statements made therein not misleading. As such, the Individual Defendants are liable to plaintiff and the Class.

54. By reasons of the conduct herein alleged, each defendant violated §11 of the Securities Act.

55. Plaintiff acquired Threshold common stock in reliance on the Registration Statements and without knowledge of the untruths and/or omissions alleged herein. Plaintiff sustained damages

when the price of Threshold common stock declined substantially due to material misstatements in the Registration Statements and Prospectuses.

56. This action was brought within one year after the discovery of the untrue statements and omissions and within three years of the date of the IPO and the Follow-on Offering.

**COUNT II**

**For Violation of Section 12(a)(2) of the Securities Act Against All Defendants**

57. Plaintiff incorporates ¶¶1-17 and 22-48 and 50-56 by reference herein. This Count is brought by plaintiff pursuant to §12(a)(2) of the Securities Act, 15 U.S.C. §77l(a)(2), on behalf of all purchasers of Threshold common stock in the IPO and Follow-on Offering. For purposes of this Count, plaintiff affirmatively states that he does not claim that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

58. Defendants were sellers and offerors and/or solicitors of purchasers of the Threshold common stock offered pursuant to the IPO and Follow-on Offering Prospectuses. Defendants issued, caused to be issued, and/or signed the Registration Statements in connection with the IPO and the Follow-on Offering. The Registration Statements contained Prospectuses that were used to induce investors, such as plaintiff and the other members of the Class, to purchase Threshold common stock.

59. The Prospectuses contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted material facts required to be stated therein. The Individual Defendants' actions of solicitation included participating in the preparation of the false and misleading Prospectuses.

60. As set forth more specifically above, the Prospectuses contained untrue statements of material fact and omitted to state material facts necessary in order to make the statements, in light of circumstances in which they were made, not misleading.

61. Plaintiff and the other Class members did not know, nor could they have known, of the untruths or omissions contained in the Prospectuses.

62. The defendants were obligated to make a reasonable and diligent investigation of the statements contained in the Prospectuses to ensure that such statements were true and that there was no omission of material fact required to be stated in order to make the statements contained therein not misleading. None of the defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Prospectuses were accurate and complete in all material respects. Had they done so, these defendants could have known of the material misstatements and omissions alleged herein.

63. This claim was brought within one year after discovery of the untrue statements and omissions in the Prospectuses and within three years after Threshold common stock was sold to the Class in connection with the IPO and the Follow-on Offering.

64. By reason of the misconduct alleged herein, the defendants violated §12(a)(2) of the Securities Act and are liable to plaintiff and Class members who purchased or acquired Threshold common stock in the IPO and/or the Follow-on Offering pursuant to the Prospectuses, each of whom has been damaged as a result of such violation.

## COUNT III

### For Violation of Section 15 of the Securities Act Against the Individual Defendants

65. Plaintiff incorporates ¶¶1-17, 22-48 and 50-64 by reference herein. This Count is asserted by plaintiff against the Individual Defendants. For purposes of this Count, plaintiff

affirmatively states that he does not claim that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

66. Throughout the Class Period, the Individual Defendants acted as controlling persons of Threshold within the meaning of §15 of the Securities Act. By reason of their stock ownership, senior management positions and/or directorships at the Company, as alleged above, these defendants, individually and acting pursuant to a common plan, had the power to influence and exercised the same to cause Threshold to engage in the conduct complained of herein. By reason of such conduct, the Individual Defendants are liable pursuant to §15 of the Securities Act.

**COUNT IV**

**For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants**

67. Plaintiff incorporates ¶¶1-49 by reference herein.

68. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

69. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Threshold common stock during the Class Period.

70. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Threshold common stock. Plaintiff and the Class would not have purchased Threshold common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

71. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Threshold common stock during the Class Period.

## COUNT V

### For Violation of Section 20(a) of the Exchange Act Against All Defendants and Threshold

72. Plaintiff incorporates ¶¶1-49 and 67-71 by reference herein.

73. The Individual Defendants acted as controlling persons of Threshold within the meaning of §20(a) of the Exchange Act. By reason of their positions with the Company and their ownership of Threshold common stock, the Individual Defendants had the power and authority to cause Threshold to engage in the wrongful conduct complained of herein. Threshold controlled the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Threshold are liable pursuant to §20(a) of the Exchange Act.

## CLASS ACTION ALLEGATIONS

74. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Threshold common stock during the Class Period (the "Class"). Excluded from the Class are defendants.

75. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to

the parties and the Court. Threshold has more than 37 million shares of stock outstanding, owned by hundreds if not thousands of persons.

76. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) Whether the Securities Act was violated by defendants;

(b) Whether the Exchange Act was violated by defendants;

(c) Whether defendants' statements omitted and/or misrepresented material facts; and

(d) the extent of damage sustained by Class members and the appropriate measure of damages.

77. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

78. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

79. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

**PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;

B. Awarding plaintiff and the members of the Class damages, interest and costs;

C. With respect to Count II, ordering rescission or recissory damages for purchasers of Threshold common stock in the IPO and Follow-on Offering;

D. Awarding plaintiff reasonable costs and attorneys' fees; and

E. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: July 5, 2007

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